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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,031	01/11/2002	Stephen F. Badylak	3220-69262	9094

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EXAMINER	
PREBILIC, PAUL B	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 06/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/044,031	BADYLAK ET AL.	
	Examiner	Art Unit	
	Paul B. Prebilic	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2006*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 11, and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Abraham et al (US 5,993,844). Abraham anticipates the claim language where Abraham states that the final product is "endotoxin free" such that it is within the claimed range of less than 12 endotoxin units per gram; see column 8, line 55 to column 9, line 13 and column 4, line 49 to column 5, line 6.

The effective filing date of the present claims is August 22, 1997 because support for the range of "an endotoxin level of less than 12 endotoxin units per gram" is not present in either provisional application 60/024,693 or 60/024,542. Rather, the apparently narrower range of "essentially zero bioburden level" is supported in these applications.

In addition, present claims 4-6 do not have support from the provisional applications because there is no clear mention of the number of colony forming units thereof. Furthermore, claim 13 does not have clear support from the provisional applications; see page 2, line 19 of 60/024,693. Additionally, claims 9 and 15 have features that are not supported by the provisional applications.

With regard to support for claim 3 in provisional application 60/024,542, the Examiner concluded that support is lacking because although "5 EU/g" is set forth, the meaning of "EU/g" is not explained anywhere in the provisional application, and it cannot be assumed to mean "endotoxin units per gram."

With regard to claim 14, Applicants are directed to column 9, lines 13-24 of Abraham.

Claims 7-10, and 16-20 are rejected under 35 U.S.C. 102(e) as anticipated by Abraham et al (US 5,993,844) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Abraham et al (US 5,993,844) alone. Abraham reasonably discloses the claimed invention as explained supra but fails to clearly disclose the product-by-process steps recited in the claims. However, the claimed product appears to be identical to the product disclosed by Abraham such that the claimed invention is considered anticipated thereby.

Alternatively, since the present claims contain product-by-process limitations, it is not explicitly clear that the product resulting from these process steps results in a product that is identical or substantially identical to that of Abraham. However, even if the process steps result in a different product from that of Abraham, the Examiner asserts that the difference is slight such that the claimed invention would have been considered obvious in view of Abraham alone; see MPEP 2113 that is incorporated herein by reference thereto.

With regard to claim 16, the tela submucosa claimed is inherently present in the tissue of Abraham since the same tissue as claimed is purified by Abraham.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abraham et al (US 5,993,844) alone. Abraham meets the claim language as explained in the rejection of base claim 1, but fails to disclose a tubular, tendon, or ligament form of the implant matrix. However, the Examiner asserts that a tubular, tendon, or ligament form of the Abraham implant matrix would have been considered obvious to an ordinary artisan since any body part (see column 4, lines 31-48) including tubular or ligament tissues (arteries, veins, intestines, heart valves, dermis, and ligaments; see column 8, lines 55-57) can be used to replace any portion of the patient's body in need thereof.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abraham et al (US 5,993,844) in view of Braun (US 3,562,820). Abraham meets the claim language as explained in the rejection of base claim 1 but fails to disclose strips of submucosa fused together as claim. However, Braun teaches that it was known to use strips of tissue fused together to form implants; see the abstract and the figures. Therefore, it is the Examiner's position that it would have been obvious to fuse two or more strips of the Abraham tissue matrix together in order to make a stronger or thicker

tissue implant to adapt it to the implant site as implicitly suggested by Braun.

Interference Sought

It is noted that the Applicant are seeking to provoke an interference with another assignee of the same subject matter. As of August 12, 2004, an Applicant seeking to provoke an interference has been required to provide the information required by new rule 37 CFR 41.202; see the attached sheet to the previous Office action from the Federal Register, Vol. 69, No. 155, published August 12, 2004. Although an Applicant may have filed or attempted to provoke an interference prior to this date, it is the Examiner's understanding that the Board of Patent Appeals and Interferences is requiring all Applicants to comply with the new rule regardless of when the attempt was first presented.

With regard to the elements of Rule 37 CFR 41.202, particular attention is required for sections (a)(4) and (d). Failure to provide a thorough account of these items may result in delay in the process or in failure to prevail in decision.

Response to Arguments

Applicant's arguments filed February 27, 2006 have been fully considered but they are not persuasive.

The Applicants argue that collagen-based matrix structure" is specially defined in the specification requiring "one or more naturally occurring components including glycoproteins, glycosaminoglycans, and proteoglycans and/or growth factors" by referring to page 14, lines 1-2 of the specification. However, upon review of the entire paragraph bridging pages 13 and 14, it is clear that no special definition is being

invoked. An inventor may choose to be his own lexicographer if he defines the specific terms used to describe the invention 'with reasonable clarity, deliberateness, and precision.' see *Teleflex, Inc. v. Ficosa No. Am. Corp.*, 63 USPQ2d 1374, 1381 (Fed. Cir. 2002). In this case, the definition is clearly one of exemplification and is not clear and deliberate as required.

Furthermore, the Applicants' arguments asserting that Abraham lacks all these components is not persuasive and does not provide any actual proof. For these reasons, the rejection has been maintained.

With regard to the argument that "EU/g" is will known in the art, the Examiner is not convinced of this fact because the Applicants only provided one reference to support their argument so it cannot be said to be well known to the art. Furthermore, the reference provided was not even to the present art of tissue implants in that it is directed to endotoxin levels in timber. For these reasons, the claim 3 rejection has been maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Prebilic
Primary Examiner
Art Unit 3738